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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
EPPS -SMITH, JANET L	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,514	MATSUI ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Smith	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03-20-2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 1-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04-06-09.

2. Applicant's election without traverse of Group II, claims 13-26 in the reply filed on 04-06-09 is acknowledged.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 14-15, 17, 19, 21-22, 24, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 14 and 17 recite the term "substantially," the metes and bounds of this phrase are vague and indefinite, the ordinary skilled artisan would not be able to ascertain the scope of the claimed invention due to the vagueness of this term.

6. Claims 19, 21-22, 24, and 26 recite the phrase "adapted for use," the metes and bounds of this phrase are vague and indefinite, the ordinary skilled artisan would not be able to ascertain the scope of the claimed invention due to the vagueness of this term.

7. Claim 15 recites "wherein the outer layer of the plurality of the bacterial magnetic particles binds with the peptides." Claim 15 depends from claim 13, however there is lack of antecedent basis of the phrase "wherein the outer layer of the plurality of the

bacterial magnetic *particles*" in claim 13. Claim 13 recites "wherein the outer layer of the plurality of the bacterial magnetic nanocrystals..."

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 13-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mao et al. (US 6,975,063) and Gazit et al. (US 7504383) in view of Ferré et al. (WO2005/019263 A1; ¶ numbers are taken from the PGpub document US20070276131) and Lee et al. (Feb. 2004; Other Condensed Matter: http://arxiv.org/abs/cond-mat/0402204).

10. Claim 13 and those claims dependent therefrom recite the following: "[A] magnetic nanotube comprising: a plurality of bacterial magnetic nanocrystals, each of the plurality of bacterial magnetic nanocrystals comprising an outer layer; a nanotube having an interior surface and an exterior surface, the nanotube being able to absorb the bacterial magnetic nanocrystals; wherein the plurality of bacterial magnetic nanocrystals are contacted on at least one of the interior and the exterior surface of the nanotube.

11. Mao et al. describe a process for the metallization of carbon nanotubes. In one embodiment *magnetite* Fe_3O_4 is applied to carbon nanotubes as a coating. Mao et al. further teaches: "One suitable method of depositing magnetite on carbon nanotubes

involves preparing an aqueous solution comprising a mixture of Fe(II) and Fe(III) halides and then reacting this with ammonium hydroxide in the presence of carbon nanotubes. The iron then precipitates out of solution as Fe_3O_4, coating the carbon nanotubes in the process. A surfactant may be employed to facilitate dispersion of the carbon nanotubes within this solution." (col. 9, lines 1-32)

12. Gazit et al. teach the design of peptide nanostructures, including nanotubes (see col. 23, lines 50-57), which are used to encapsulate materials, wherein said materials include, *magnetite* (see col. 12, lines 21-23; col. 23, lines 38-42). Gazit et al. further teaches that "In order to generate the filled nanostructure of the present invention, the foreign material is introduced into the internal cavity of the tubular or spherical nanostructure, to encapsulate the material in nanostructure. A method of filling is described in the Example section which follows, exhibiting casting of *nanowires*, using as a mold, the *nanotubes* of the present invention." (see also, col. 23, lines 51-57)

Col. 25 of Gazit et al. discloses the following aspects of their invention involving the use of the encapsulated nanostructures of their invention for positioning a target molecule at a predetermined location and for delivering an agent to a subject:

> " Referring now to the drawings, FIG. 1 is a flow chart diagram of a method of positioning a target molecule at a predetermined location. The method comprises the following method steps in which in a first step, a magnetic nanowire is provided. The magnetic nanowire is preferably formed of a magnetic material at least partially enclosed by the peptide nanostructure of the present invention. According to a preferred embodiment of the present invention, the nanostructure has at least one segment associated with a functional group or ligand, which are capable of binding to the target molecule.
>
> Representative examples of functional groups which are contemplated include, without limitation, thiols, disulfides, cyanides, amines, carboxylic acids, phosphonates, siloxanes or hydroxamic acids. Representative examples of ligands which are contemplated include, without limitation, proteins, fibronectin, DNA, RNA, enzymes, ribozymes, hydrophobic materials, hydrophillic materials, cells, tissue, microorgantisms, bacteria, viruses and chemoattractant.
>
> In a second step of the method, the magnetic nanowire is bound to the target molecule, and in the third step, the magnetic nanowire (and the target molecule to which it bounds) is exposed to a magnetic field. As stated, when a magnetic material is placed in a magnetic field,

> its magnetic properties are manifested by forces acting thereon. Thus, by a judicious selection of the magnetic field (magnitude and direction) the nanowire, under the influence of the magnetic force, may be moved, together with the target molecule, to the desired location.
>
> According to another aspect of the present invention, there is provided a method of delivering an agent to a subject. The method comprises the following method steps which are illustrated in the flowchart diagram of FIG. 2."

However, neither Mao et al. nor Gazit et al. do not teach wherein the source of magnetite is derived from bacterial magnetic nanocrystals synthesized from bacteria selected from the genus *Magnetospirillum*.

Ferré et al. et al. teach the following: [0001] The present invention relates to the field of macromolecular assembly and capture, e.g. to the process of refolding of proteins, hybridization of nucleic acid, nucleic acid analogues, and protein-nucleic acid chimera, aggregation of carbohydrates, and assembly of *nanostructures/nanomaterials*. The present invention provides a continuous process for assembly of *macromolecular substances and capture of a macromolecular assembly of one or more macromolecular substances*. The present invention also provides a system suitable for the process.

[0045] The term "*macromolecular substances*" covers a broad range of commercially and clinically important molecules, such as proteins, carbohydrates, nucleic acids (for example RNA and DNA), nucleic acid analogues (for example PNA (peptide nucleic acids) and LNA (locked nucleic acids)), protein-nucleic acid chimera, and nanomaterials (for example nanoscale biomimetic materials, nanomotors (e.g. ATP motors), nano drug delivery systems, nanobeads, *carbon nanotubes and nanowires*).

[0075] Generally, methods for preparation of magnetic particles are described in the art and the person skilled in the art will be able to select and test appropriate combinations of coating, activation, and coupling chemistries. [0076] In a specific

embodiment of the present invention *magnetotactic bacteria*, such as but not limited to *Magnetospirillum*, expressing suitable surface exposed ligands, could be used as the capturing agent in the present invention. The surface functionality of the bacteria could be modified in order to either capture the assembled or the unassembled molecule.

Lee et al. (2004), teach the assembly of magnetic nanoparticles by micromanipulation of magnetotactic bacteria. In one particular embodiment, the reference describes the magnetotactic bacteria *Magnetospirillum magnetotacticum* as a source for magnetite (Fe_3O_4).

It would have been obvious to the ordinary skilled artisan at the time of the instant invention to modify the teachings of Mao et al. and Gazit et al. with the teachings of Ferré et al. and Lee et al. in the design of the instant invention. One of ordinary skill in the art would have been motivated to substitute the magnetite used to modify the nanostructures of Mao et al. and Gazit et al. with the functionally equivalent magnetite produced from the magnetotactic bacteria described in Ferré et al. and Lee et al. since the magnetite described in the references are described as structurally equivalent to that disclosed in Mao et al. and Gazit et al. See MPEP § 2144.06 [R-6], which describes the substitution of art recognized equivalents for use in the same purpose.

Regarding the rationale for combining prior art elements according to known methods to yield predictable results, all of the claimed elements were known in the prior art and one skilled in the art could have combined the element as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633